

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

ALLERGAN USA, INC., ALLERGAN	)	
HOLDINGS UNLIMITED COMPANY,	)	
ALLERGAN PHARMACEUTICALS	)	
INTERNATIONAL LIMITED and	)	
JANSSEN PHARMACEUTICA NV,	)	
	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. _____
	)	
SUN PHARMACEUTICAL INDUSTRIES	)	
LTD.,	)	
	)	
Defendant.	)	

**COMPLAINT**

Plaintiffs Allergan USA, Inc., Allergan Holdings Unlimited Company, Allergan Pharmaceuticals International Limited, and Janssen Pharmaceutica NV (collectively, “Plaintiffs”), for their Complaint against Defendant Sun Pharmaceutical Industries Limited, (collectively, “Sun”), hereby allege as follows.

**PARTIES**

1. Plaintiff Allergan USA, Inc. is a Delaware corporation having a principal place of business at 5 Giralda Farms, Madison, New Jersey 07940.
2. Plaintiff Allergan Holdings Unlimited Company is an Irish corporation having a principal place of business at Clonshaugh Business & Technical Park, Dublin 17, Ireland.
3. Plaintiff Allergan Pharmaceuticals International Limited is an Irish corporation having a principal place of business at Clonshaugh Business & Technical Park, Dublin 17, Ireland (referred to herein, together with Allergan USA, Inc., and Allergan Holdings Unlimited Company, as “Allergan”).

4. Plaintiff Janssen Pharmaceutica NV is a Belgian corporation having a principal place of business at Turnhoutseweg 30, Beerse B-2340, Belgium (“Janssen”).

5. Upon information and belief, Defendant Sun Pharmaceutical Industries Limited (“Sun”) is a corporation organized and existing under the laws of India, having a principal place of business at Sun House, Plot. No. 201 B/1, Western Express Highway, Goregaon (E), Mumbai, Maharashtra, India 400. Upon information and belief, Defendant Sun Pharmaceutical Industries Limited manufactures, imports, and/or distributes numerous generic drugs for sale and use throughout the United States, including in this judicial district.

### **NATURE OF THE ACTION**

6. This is a civil action for the infringement by Sun of U.S. Patent No. 7,741,356 (“the ’356 patent”). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and arises from Sun’s recent amendment of Abbreviated New Drug Application (“ANDA”) No. 213447 to challenge the ’356 patent and seek to commercialize generic versions of Plaintiffs’ Viberzi<sup>®</sup> brand eluxadoline tablets throughout the United States, including in this judicial district, before the expiration of the ’356 patent, including any extensions or exclusivities.

### **JURISDICTION AND VENUE**

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

8. This Court has personal jurisdiction over Sun by virtue of the fact that, *inter alia*, Sun has committed, or aided, abetted, induced, contributed to, and/or participated in the commission of, a tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs in Delaware. Sun has participated in the preparation, filing, and/or amendment of an

ANDA seeking approval to market and sell a generic version of Plaintiffs' branded product, Viberzi®, and has distribution channels and plans to market and sell its generic product throughout the United States, including in this judicial district, before the '356 patent expires, including any extensions or exclusivities. This Court has personal jurisdiction over Sun for the additional reasons set forth below and for other reasons that will be presented to the Court if such personal jurisdiction is challenged.

9. This Court has personal jurisdiction over Defendant Sun Pharmaceutical Industries Limited by virtue of, *inter alia*, its systematic and continuous contacts with Delaware. Upon information and belief, Sun Pharmaceutical Industries Limited is amenable to litigating in this forum based on Sun Pharmaceutical Industries Limited's conduct in multiple prior litigations in this District. For example, Sun did not contest this Court's jurisdiction in Plaintiffs' previously filed civil action regarding Sun's ANDA No. 213447, Civil Action No. 19-1727-RGA.

10. Venue is proper in this judicial district as to Sun pursuant to 28 U.S.C. §§ 1391 and 1400(b).

### **THE PATENTS**

11. On June 22, 2010, the '356 patent, titled "Compounds As Opioid Receptor Modulators," was duly and lawfully issued by the United States Patent and Trademark Office ("USPTO"). The USPTO issued certificates of correction for the '356 patent on September 23, 2014 and May 12, 2020. Janssen is the sole owner of the '356 patent. Allergan is the exclusive licensee of the '356 patent with respect to manufacturing and commercializing therapeutic products containing eluxadoline worldwide, including in the United States. A copy of the '356 patent, including its certificate of corrections, is attached hereto as Exhibit A.

12. Allergan Holdings Unlimited Company holds New Drug Application (“NDA”) No. 206940 for Viberzi® brand eluxadoline tablets. Viberzi® is approved for the treatment of irritable bowel syndrome with diarrhea (“IBS-D”) in adults. The ’356 patent is listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* (“the Orange Book”) for Viberzi®, along with thirteen other patents.

13. Allergan USA, Inc. is the exclusive distributor of Viberzi® in the United States.

**ACTS GIVING RISE TO THIS ACTION**

14. Upon information and belief, on or before July 31, 2019, Sun submitted ANDA No. 213447 to the U.S. Food and Drug Administration (“FDA”) under § 505 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 213447 seeks FDA approval for the commercial manufacture, use, and sale of generic oral tablet products containing 75 mg and 100 mg of eluxadoline as the active ingredient (“the Sun Generic Products”).

15. Pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, ANDA No. 213447 previously included allegations that the claims of U.S. Patent No. 9,675,587 (“the ’587 patent”) and U.S. Patent No. 10,188,632 (“the ’632 patent”) were invalid, unenforceable, and/or would not be infringed by the manufacture, use, or sale of the Sun Generic Products. Plaintiffs received written notification of ANDA No. 213447 and its previous § 505(j)(2)(A)(vii)(IV) allegations with respect to the ’587 patent and ’632 patent no earlier than July 31, 2019, and timely filed suit with respect to those patents on September 13, 2019 in *Allergan USA, Inc. et al. v. Sun Pharmaceuticals Industries Ltd. et al.*, Civil Action No. 19-1727-RGA (D. Del.).

16. Upon information and belief, Sun recently amended ANDA No. 213447 to include, for the first time, allegations that the claims of the ’356 patent are invalid and/or will not be infringed by the manufacture, use, or sale of the Sun Generic Products. None of the Plaintiffs

received written notification of Sun's amendment of ANDA No. 213447 to add § 505(j)(2)(A)(vii)(IV) allegations with respect to the '356 patent any earlier than October 8, 2020.

17. Even with its recent amendment of ANDA No. 213447 to include § 505(j)(2)(A)(vii)(IV) allegations with respect to the '356 patent, Sun has still not submitted any § 505(j)(2)(A)(vii)(IV) allegations for eleven patents listed in the Orange Book for Viberzi®. Those unchallenged patents do not expire before July 7, 2028. As a result, under the Hatch-Waxman Act, Sun cannot offer to sell or otherwise commercialize any of the generic products described in ANDA No. 213447 prior to July 7, 2028 regardless of the outcome of this action.

18. Sun's amendment of ANDA No. 213447 to include § 505(j)(2)(A)(vii)(IV) allegations with respect to the '356 patent constitutes infringement of at least Claims 33, 35, and 40 of the '356 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Sun commercially manufactures, uses, offers for sale, or sells within the United States, or imports into the United States, the Sun Generic Products, or induces or contributes to any such conduct, it would further infringe at least Claims 33, 35, and 40 of the '356 patent under 35 U.S.C. § 271(a), (b), and/or (c).

19. Sun has infringed the identified claims of the '356 patent under 35 U.S.C. § 271(e)(2)(A), and will further infringe one or more of these claims under 35 U.S.C. § 271(a), (b), and/or (c) if the Sun Generic Products are commercially made, used, offered for sale, or sold in the United States, or imported into the United States, because, *inter alia*, the Sun Generic Products will meet each and every element of at least Claims 33, 35, and 40 of the '356 patent, either literally or under the doctrine of equivalents.

20. Upon information and belief, Sun has participated in, contributed to, aided, abetted, and/or induced infringement of the '356 patent and/or will participate in, contribute to, aid, abet, and/or induce infringement of the '356 patent once the Sun Generic Products are commercially made, used, offered for sale, or sold in the United States, or imported into the United States.

21. Upon information and belief, Sun was aware of the '356 patent prior to filing ANDA No. 213447 in 2019 and did not include any § 505(j)(2)(A)(vii)(IV) allegations with respect to the '356 patent at that time. Upon information and belief, Sun was aware of the '356 patent prior to amending ANDA No. 213447 in 2020 to include § 505(j)(2)(A)(vii)(IV) allegations with respect to the '356 patent.

22. Sun's actions render this an exceptional case under 35 U.S.C. § 285.

23. Plaintiffs will be irreparably harmed by Sun's infringement of the '356 patent unless that infringement is enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

### **PRAYER FOR RELIEF**

**WHEREFORE**, Plaintiffs pray for judgment as follows:

- A. That Sun has infringed the '356 patent under 35 U.S.C. § 271(e)(2)(A);
- B. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Sun's ANDA No. 213447 shall not be earlier than the expiration date of the '356 patent, including any extensions or exclusivities;
- C. That Sun, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, are preliminarily and permanently enjoined from commercially manufacturing, using, offering for sale, or selling in the United States, or

importing into the United States, the Sun Generic Products, and any other product that infringes or induces infringement or contributes to the infringement of the '356 patent, prior to the expiration of the '356 patent, including any extensions or exclusivities;

D. That Plaintiffs be awarded monetary relief if Sun commercially makes, uses, offers for sale, or sells in the United States, or imports into the United States, any of the Sun Generic Products, or any other product that infringes or induces infringement or contributes to the infringement of the '356 patent, prior to the expiration of the '356 patent, including any extensions or exclusivities, and that such monetary relief be awarded to Plaintiffs with prejudgment interest;

E. That this is an exceptional case under 35 U.S.C. § 285 and that Plaintiffs be awarded the attorney fees, costs, and expenses that they incur prosecuting this action;

F. That Plaintiffs be awarded all of the relief they seek in their related litigation against Sun, *Allergan USA, Inc. et al. v. Sun Pharmaceuticals Industries Ltd. et al.*, Civil Action No. 19-1727-RGA (D. Del.); and

G. That Plaintiffs be awarded such other and further relief as this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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